

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

May 3, 2002

MEMORANDUM:

Subject: Efficacy Review EPA Reg. No. 72674-22
Baquacil Ultra Swimming Pool & Sanitizer/Fungicide
DP Barcode 280085
Case No. 066322

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Applicant: Avecia Biocides
1405 Foulk Road
PO Box 15457
Wilmington, DE 19650-5457

Formulation Label:

% by wt.

Active Ingredient(s)

Poly(iminoimidocarbonyliminoimidocarbonyl- iminohexamethylene hydrochloride).....	20%
Inert ingredients.....	80%
Total.....	100%

I. Background:

The registrant has submitted an efficacy field study to confirm the effectiveness of the product against microbial overgrowth in residential swimming pools. The study, which collected data in two residential pools during the months of June through September 2001 (the designated swimming season in the area), was contained in one document, MRID 455666-01.

II. Use Directions:

This product is not compatible with chlorine, so all chlorine must be removed from the pool if chlorine products have been previously used. A chlorine test must be made, and if chlorine is present, a neutralizer must be added to the water until all the chlorine is removed. If the water is cloudy, an indication of algae growth, add one gallon of *BAQUACIL Shock and Oxidizer* per 10,000 gallons of water. Filter overnight. To get started with this product, the filter must be cleaned and the pH adjusted to a range of 7.2-7.8. Add *BAQUACIL ULTRA System Start-up* according to package directions. Add 56 oz. of product per 10,000 gallons of water to obtain a initial reading of 50 ppm. Filter overnight. After 24 hours, use test strips to check the pool's pH and *BAQUACIL ULTRA Sanitizer* reading, and adjust if necessary. Thereafter, a weekly check of the product's concentration, pH, and total alkalinity must be made. The product concentration should be between 30-50 ppm, and must never fall below 30 ppm. To raise concentration 10 ppm, add 14 oz. per 10,000 gallons water. Every week one pouch of *BAQUACIL ULTRA Oxidizer* should be added per 10,000 gallons of water. This product is also incompatible with algicides which contain copper and many detergents.

III. Agency Standards for Proposed Change:

The Agency standards for swimming pool disinfectants are found in DIS-TSS-12 and are based on the *Association of Official Analytical Chemists (AOAC) Method for Water Disinfectants for Swimming Pools* or with slight modifications (e.g., pH) against both *Escherichia coli* and *Enterococcus faecalis*. The lowest concentration of the test product which provides results equivalent to those of the sodium hypochlorite control is the lowest concentration of the product that can be considered effective.

Specific field test requirements are listed in Section (3). The following information must be provided about the pool used in the test: the design of the pool, the recirculation and filter system, and the water capacity. Also required are the daily bather load, the amount and identification of all chemicals added to the pool with specific information about the time, the site, and the method of the addition. Chemical ranges of pool water characteristics such as pH, nitrogenous substances, metal, and hardness must also be listed, and temperature and clarity must be determined daily. The meteorological data which includes daily air temperature, rainfall, and hours of sunlight must be recorded. A minimum of 144 water samples for bacteriological analysis must be taken during the test period. Samples should be collected from opposite sides of the pool at the shallow level just below the surface of the water and as remote as possible from the inlets, preferably at midpoints between the inlets. Samples should be collected at times when the number of persons using the pool during the preceding hour was at least 50% of the maximum bather load, and the number of persons in the pool at the time of collection is at least equal to 25% of the maximum bather load. Pertinent chemical characteristics of the pool water at the sampling site should also be determined at the time of collection. The concentration of the product in the pool water must be monitored daily at the same time intervals that bacteriological assay samples are collected. The method used

to monitor the concentration of the antimicrobial agent in ppm must be stated.

The performance standard for field tests is that the product must demonstrate that less 15% of the total samples collected will have a standard plate count of 200 col./1.0 ml at 35° C and the most probable number (MPN) shall be less than 2.2 org./100 ml. If the membrane filter test is used, there should be no more than 1.0 enterococcal organisms / 50 ml.

IV. Summary of Submitted Study:

The field test for *BAQUACIL ULTRA* Sanitizer was conducted in summer of 2001 in two residential pools in Wilmington, DE. Good Laboratory Practices were followed during the course of the study. The swimming season in this area is ordinarily considered to begin when the public schools close for the summer until Labor Day, so the 4-month testing season for this field trial was from the first of June thru September. Actual sample collection occurred over three calendar months from the first of June until the first Monday in September. One lot of product (1031B-038), provided by the registrant, was used throughout the testing season. The entire lot of product was stored in a wood frame shed without air-conditioning at the rear of the Avecia New Castle Site pool shed. One bottle of the lot was sent to Avecia in Blacked, Manchester, UK which performed the chemical characterization using GLP. When product was needed, it was transferred from the shed to a minivan also used for pool side testing. The temperature in the minivan was approximately that of the pool shed. To verify that the product was stable under the storage conditions, another bottle from the same lot was sent to Blackall at the conclusion of the study in September for the repeat chemical characterization testing.

One pool, designated by the owner's name Lewis, was an in-ground rectangular 512 sq. ft. pool with a vinyl liner and a capacity of 25,000 gallons. The other, designated "Revel" was a 18 ft. circular on-ground pool with a capacity of 7500 gallons. Both had electric circulating pumps and sand filters. Both had been using *BAQUACIL* for at least 4 years. Both pools were converted to *BAQUACIL Ultra* following label directions prior to the start of the collection phase.

The method used to analyze the pool waters was the PINPOINT water system. This apparatus is a portable, battery-powered colorimeter system which analyzes hydrogen peroxide concentration, pH, alkalinity, calcium hardness, copper, and iron as well as the concentration of PH.B. The curette used are pre-loaded with reagents. Samples are added by pipetting a 3 ml aliquot into each curette. Microbial counts in the study were made using Millipore's Milliflex system which uses a 0.45 micron filter. The membranes in the filter are transferred after filtration to cassettes which contain appropriate growth medium. The Milliflex system uses a 120-v portable vacuum manifold. Both these systems are convenient to use in field testing. In this test, the equipment was transferred to the two test pools in the minivan. Sample testing was processed either pool side or in the van.

The antimicrobial product was added to the pool by pouring into the pool around the perimeter. The concentration of the product was maintained at 30-50 ppm (6-10 ppm PMHB). The pool operator determined, based on those limits, when additional product was needed. Water samples were collected in the following sequence.

- a. A chemical water sample was collected and analyzed before swimmers entered the pool.
- b. At this time water temperature and clarity (0-4 where 4 is sparkling and 0 was cloudy) were recorded, and if no adjustments were needed, the values for water balance, temperature, and clarity were considered.

- valid for the day. PHMB sanitizers are much less susceptible to depletion than chlorine due to bather load and sunlight.
- c. If adjustments were needed, they were made. After a minimum of 2 hours after adjustment, the water was re-analyzed. Values obtained were considered valid if no further adjustment was needed.
 - d. Microbial samples were collected using aseptic techniques and sterile containers and were processed before swimmer use began. This reading served as the microbial baseline.
 - e. The time swimmers first entered the pool was noted.
 - f. An additional water sample will be collected fifteen minutes after the swimmers began to use the pool. The time and the number of swimmers was recorded.
 - g. Subsequent samples were collected, preferably at 15-30 minute intervals. Up to twelve samples were collected in one day. When residential pool parties were being held, a total of 20 samples might be collected at intervals of 20 minutes or longer. The time and number of swimmers in the pool at the time were recorded.
 - f. Following the collection of the last microbial sample for the day, a chemical water sample was collected in order to measure the level of sanitizer present.

Microbial water samples were processed in the portable field lab as soon as possible after collection, and samples were processed in duplicate. Neutralization of (P.H.B.) in the samples was achieved by using 10% by volume of lecthin/tween. The inoculated cassettes were transferred to lab incubators within five hours of processing. The time of the placement of plates in the incubator was defined as the initiation of incubation. Bacterial plate counts were made for total heterotrophic count, total coliforms, and for *Enterococcus faecalis* (fecal strep), *E. coli*, *Ps. aeruginosa*, and *Staphylococcus aureus*. Determination of the number present of the first two organisms is required by Agency standards. Avecia, the sponsor of the study, required the addition of counts of Staphylococci and Pseudomonas to the protocol. The media used to determine the number of various organisms were as follows: total count, mTGE media, coliforms, Endo agar, fecal strep, KF agar, *Staph. aureus*, Mannitol salt agar, and tryptic soy agar with addition of phenol red, sulfa pyridine, kanamycin, nalidixic acid and cycloheximide (TSPA) was used to enumerate the samples for *Pseudomonas aeruginosa*. In addition to the required acceptable counts for fecal strep and *E. coli* the acceptable counts for the Avecia organisms were 50 CFU/100 ml of *Staph* and 2 CFU/100 ml of *Pseudomonas*. A sample was considered bacteriologically acceptable when the average bacterial count was less than or equal to the Maximum Permissible Level for all five micro- biological categories.

The US National Weather Service in Wilmington, DE collected the meteorological data, and it was downloaded from the NWS website at Philadelphia/Mt. Holly, NJ. The water parameters (range of chemical characteristics) maintained during the study were: pH, 7.0-8.4, ideally between 7.2-7.8, calcium hardness, 150-300 ppm, ideally between 180-275 ppm, total alkalinity, 60-175 ppm and ideally 80-150 ppm; BAQUACIL Ultra Shock and Oxidizer, <500 ppm as product as product and ideally 25-100 ppm as product; copper, <0.3 ppm and ideally 0.0pp, and iron, <0.3 as product and ideally as 0.0. At various times in the study the PINPOINT copper and iron Unit Dose Vials (UDV's) became unreliable. This appeared to be a reagent problem with these specific UDV's, and had no impact of the study or the reliability of the other data generated using the PINPOINT system.

The bather load was calculated according to the method of the Council of National Cooperation in Aquatics. In this method, the maximum permissible number of bather is defined

as one bather per 25 square feet of surface area. Using this method the bather load for the two pools used in this study were as follows:

Lewis pool

16' x 32' = 512 sq.ft. Maximum permissible bather load $512/25 = 23$ (22.88)
 25% load = 6 (5.77 rounded to whole number) 50% load = 12

Revel pool

18' circular = 254.34 sq.ft. Maximum permissible bather load $254.32/25 = 10$
 25% load = 2-3 50% = 5

A total of 172 water samples were collected during the study. Of the samples collected 162 were collected when the sanitizer was at the acceptable level of 30-50 ppm and were defined as qualified and used to evaluate effectiveness of the product. Of the acceptable collections of 162, 140 samples were collected when bathers were present and 124 were collected when there were at least 25% of the maximum bather load present in the pool.

Deviations (5 total) from the accepted protocol were listed on pages 39-41 in the study, but none were felt by the Study Director to have any adverse effect on the efficacy of the product.

The results of the microbiological samples are as follows:

Summary of results from all qualified microbiological samples where Ultra was in range, inc. pre- and post-swim samples. These are the organisms required by the EPA

	Total Samples	Total Count		Total Coliforms		Fecal Strep		Cumulative	
		#	%	<i>E. coli</i> #	%	<i>Ent. faecalis</i> #	%	#	%
Lewis pool	66	66	100.00%	66	100.00%	66	100.00%	66	100.00%
Revel pool	96	96	100.00%	66	100.00%	96	100.00%	96	100.00%
Total	162	162	100.00%	162	100.00%	162	100.00%	162	100.00%

This table shows results for the organisms required by Avecia

	Total Samples	Total Count		<i>Staph. aureus</i>		<i>Ps. aeruginosa</i>		Cumulative	
		#	%	#	%	#	%	#	%
Lewis pool	66	66	100.00%	66	100.00%	66	100.00%	66	100.00%
Revel pool	96	96	100.00%	96	100.00%	96	100.00%	96	100.00%
Total	162	162	100.00%	162	100.00%	162	100.00%	162	100.00%

All (100%) of the 162 qualified samples had bacterial counts that were acceptable and that demonstrated the effectiveness of *BAQUACIL ULTRA* against *Enterococcus faecalis*, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*.

V. Labeling:

1. The label does not state that this product may be used for residential pools. It would be helpful to the consumer if the label stated that *BAQUCIL ULTRA* is effective for both residential and commercial pools. There are directions for spas and tubs.

VI. Comments and Recommendations:

1. This field test was very comprehensive and addressed all the parameters that the Agency requires for a valid field test. The report was clear and concise.
2. The product *BAQUACIL ULTRA* demonstrated effectiveness against *Enterococcus faecalis*, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus* by controlling the specified count of these organisms at or below the maximum number permissible in at least 85% of the samples collected when the level of the agent was maintained at 30-50 ppm and all water parameters were within the stated range for sanitization.